Food and Drug Administration (FDA)

Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Advisory Committee for Reproductive Health Drugs (ACRHD) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

FDA White Oak Campus, Building 31, the Great Room, White Oak Conference Center (Rm. 1503), Silver Spring, MD

March 5, 2013

AGENDA

The committees will discuss whether the benefit of calcitonin salmon for the treatment of postmenopausal osteoporosis (thinning and weakening of bones that increase the chance of having a broken bone) outweighs a potential risk of cancer. Calcitonin salmon products approved for the treatment of osteoporosis include Miacalcin (calcitonin salmon) injection and nasal spray, submitted by Novartis Pharmaceuticals Corporation; Fortical (calcitonin salmon recombinant) nasal spray, Upsher Smith Laboratories; and the generic equivalents of these products.

8:00 a.m.	Call to Order Introduction of Committee	**Julia Johnson, MD** Chairperson, ACRHD
	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, ACRHD
	Introductory Remarks	**Hylton Joffe, MD, MMSc** Director, Division of Reproductive and Urologic Products (DRUP), Office of Drug Evaluation III (ODEIII), Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**Sponsor Presentations**	**Novartis Pharmaceuticals Corporation**
	Introduction	**John Orloff, MD** Chief Medical Officer Novartis Pharmaceuticals Corporation
	Efficacy and Safety of Calcitonin	**Paul Aftring, MD, PhD** Global Program Head Novartis Pharmaceuticals Corporation
	Putting Risk into Context	**Noel Weiss, PhD** Professor of Epidemiology University of Washington
	Novartis Proposal for Risk Minimization and Further Evaluation of Calcitonin	**John Orloff, MD** Chief Medical Officer Novartis Pharmaceuticals Corporation

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AGENDA (cont.)

9:15 a.m.	Clarifying Questions from Committee	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA Presentations**	
	Calcitonin Salmon Regulatory and Drug Use History	**Theresa Kehoe, MD** Clinical Team Leader DRUP, ODEIII, OND, CDER, FDA
	Salmon Calcitonin, Safety Signal	**CDR David Moeny, RPh, MPH, USPHS** Epidemiologist Division of Epidemiology II Office of Surveillance and Epidemiology CDER, FDA
		Janelle Charles, PhD Mathematical Statistician Division of Biometrics VII Office of Biostatistics Office of Translational Sciences CDER, FDA
	Salmon Calcitonin , Efficacy	**Stephen Voss, MD** Medical Officer DRUP, ODEIII,OND, CDER, FDA
	Salmon Calcitonin, Summary	**Theresa Kehoe, MD**
11:15 a.m.	Clarifying Questions from Committee	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Clarifying Questions for Sponsor or FDA (cont.)	
2:30 p.m.	**BREAK**	
2:45 p.m.	Committee Discussion and Questions to the Committee	
4:00 PM.	**ADJOURN**	